IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

1:13-cv-239
Janet T. Neff
U.S. District Judge

CLINTON THORN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. _____
MEDTRONIC, INC., a Minnesota corporation, and MEDTRONIC SOFAMOR DANEK USA, INC., a Tennessee corporation,	)	
	)	
Defendants.	)	

COMPLAINT

COMES NOW *Pro Se* Plaintiff CLINTON THORN ("Plaintiff"), for his claims against Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc., alleges and states the following:

I. PARTIES

1. Plaintiff CLINTON THORN is an individual who is a resident of Stanton, Michigan.

2. Defendant MEDTRONIC, INC. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

3. Defendant MEDTRONIC SOFAMOR DANEK USA, INC. is a Tennessee corporation, with its principal place of business at 2600 Sofamor Danek Drive, Memphis, Tennessee 38132.

II. JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between Plaintiff and the Defendants, and because Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs.

5. This Court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial and regular business activities in the State of Michigan and have continuously and systematically conducted business in Michigan including the marketing, selling, and promotion of the INFUSE® Bone graft product.

6. Venue is proper in this District pursuant to 28 U.S.C. § 139l(b)(1) because both defendants are corporations deemed to reside in this district pursuant to 28 U.S.C. §1391(c)(2) and plaintiff is a resident of Montcalm County.

III. BACKGROUND OF THE CASE

7. This case involves a spinal surgery in which a bio-engineered bone graft device known as the Infuse® Bone Graft ("Infuse®") was used in a posterior-approach spine surgery for Plaintiff, CLINTON THORN.

8. Infuse® was made by MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK, USA, INC. (collectively "the Medtronic Defendants" or "Medtronic") and was promoted and sold by Medtronic to be used off-label in CLINTON THORN's posterior lumbar interbody fusion (L5 - S1) on March 4, 2010 in Michigan.

9. Infuse® is approved and indicated for lumbar surgery that is performed through the abdomen (anterior). It is not approved for use in lumbar surgery through the back (posterior).When Infuse® is used off-label, such as in a posterior-approach spine surgery, it often causes"ectopic" or "exuberant" bone growth onto or around the spinal cord. When nerves are compressed by ectopic/exuberant bone growth, a patient can experience, among other side effects, intractable pain and weakness, as it did in CLINTON THORN's legs and back.

10. Medtronic either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the use of Infuse®, including but not limited to the risk of ectopic or uncontrolled bone growth. According to articles in the June 2011 issue of The Spine Journal (an international medical journal that publishes peer-reviewed research articles related to evidence-based spine care), earlier Medtronic-sponsored studies and articles inaccurately reported the safety of rhBMP-2 (the active fusion ingredient in Infuse®) by underestimating its risks.

11. For example, these Medtronic-sponsored articles omitted mention of adverse effects seen in the earliest trials of Infuse®, such as uncontrolled or ectopic bone growth, inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinaryretention, bone resorption, and implant displacement. They also omitted mention of the risks of sterility and cancer associated with rhBMP-2 use, as reported in Food and Drug Administration documents and hearings.

12. The actual rate of incidence of these serious side effects is much greater than the rate disclosed by Medtronic or these Medtronic-sponsored studies to physicians or to the public. With respect to posterior lumbar interbody fusion-which Plaintiff

CLINTON THORN underwent-Medtronic failed to disclose significant risks that it knew of or should have known of, including ectopic bone formation, radiculitis, osteolysis, and worse overall outcomes.

13. Because of Medtronic's wrongful conduct, hundreds of patients, like CLINTON THORN, underwent surgeries without knowing the risks created by off-label use of Infuse®.These patients' doctors were persuaded by Medtronic and Medtronic' s consultant "opinion leaders," who are paid physician promoters, and Medtronic sales representatives, to use Infuse® for dangerous off-label uses such as posterior lumbar fusion surgery.

14. As a result of his off-label, posterior-approach Infuse® spine surgery, CLINTON THORN suffered severe bodily injuries and lost income. He has required an April 24, 2012, revision surgery for the resulting bone growth and will require additional revision surgeries. He has also incurred a significantly higher risk of cancer.

15. Because of his off-label surgery using Infuse®, CLINTON THORN has been forced to take significant time off of work, and has great difficulty working. He suffers continuous pain in his back and legs from everyday activities.

A. The Infuse® Bone Graft Device

16. Medtronic designed and marketed Infuse® for lumbar spine fusion surgery.

17. Infuse® is a bio-engineered bone filling material containing a bone morphogenetic protein ("BMP"), and is used as an alternative to grafting a patient's own

bone, typically from the patient's hip. The purpose of Infuse® is to accomplish the same clinical outcomes as grafting a patient's own bone into these locations but without the difficulties of grafting bone from the hip and other sites, since grafting sites sometimes have side effects such as pain.

18. It uses a genetically engineered protein - rhBMP -to help fuse vertebrae in the lower (lumbar) spine in order to treat degenerative disc disease.

19. The device consists of three components split among two parts: (1) a metallic spinal fusion cage; and, (2) the bone graft substitute which consists of a genetically-engineered human protein (rhBMP-2) along with a sponge-like carrier or scaffold for the protein (manufactured from bovine collagen) that is placed inside the fusion cage.

20. The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the Infuse® bone graft component is used to form bone, which is intended to permanently stabilize (fuse) this portion of the spine.

21. During surgery, rhBMP-2 is soaked onto and binds with the absorbable collagen sponge that is designed to resorb, or disappear, over time. As the sponge dissolves, the rhBMP-2 stimulates the cells to produce new bone.

B. Background on Bone Morphogenetic Proteins in the Infuse® Bone Graft

22. The active ingredient in the INFUSE® Bone Graft is rhBMP-2, a genetically modified version of protein already present in the human body that promotes new bone growth.

23. Certain BMPs have been studied for decades because of their ability to heal bone and eliminate the need for bone graft harvesting from other parts of the body. Approximately twenty (20) BMPs have been discovered, but only six appear capable of initiating bone growth. Of these, rhBMP-2 has been studied more than any other BMP and is FDA-approved for use only in the lower (lumbar) spine, some types of tibia fractures, an some dental surgeries.

24. Naturally-occurring BMP is found within the bone itself, but only in small amounts. To provide clinically useful and reproducible amounts of isolated, human BMP, it must be genetically modified in a special facility.

25. Scientists isolated the gene for one protein (BMP-2) from bone tissue and used molecular biology techniques to create genetically engineered cells. These cells then produce large quantities of rhBMP-2.

C. The FDA Approval Process

26. Infuse® was approved by the United States Food and Drug Administration ("FDA") on July 2, 2002, for use only in the lower, or lumbar, region of the spine (at levels L4 through S 1) to treat degenerative disc disease, and was approved only for anterior-approach surgeries at L4 through S 1. That meant that it was initially approved only to be used by surgeons in spinal fusions when going in through the patient's abdomen.

27. Infuse® is also used to fill space where bone is needed in order to place dental implants (for example, dental implants with an exposed head used to secure dental

devices such as crowns, fixed bridges, or dentures.) In dental surgeries, Infuse® is used to make enough bone in the sinus area to place dental implants in the upper jaw. Infuse® is also used to increase bone in extraction sites prior to implant placement.

28. Infuse® was approved by the FDA on March 9, 2007, for dental use.

29. In addition to use in lower spine fusion surgeries and dental surgeries, Infuse® has been approved for only one other use: repair of certain tibial fractures.

30. Infuse® has never been approved by the FDA for use in other parts of the body or for use in any other type of procedure. Any such uses are "off-label" uses.

31. Physicians may use FDA-approved medical devices in any way they see fit, but companies are not permitted to promote off-label uses for their medical devices or to pay doctors inducements or kickbacks to promote off-label uses or to perform procedures using the devices off-label.

32. The use of Infuse® for posterior lumbar fusion surgery has never been approved by the FDA, and the use of this product through a posterior approach is an off-label use.

D. Infuse® is a Very Profitable Part of Medtronic's Business

33. Infuse® has become a best seller for Medtronic. One market analyst has publicly estimated that the product's sales were approximately $815 million for the fiscal year ending in April 2008. Medtronic has been depending heavily on Infuse® since sales in so many of its other products, such as cardiac defibrillators, have slowed because of the recalls of those defective defibrillators.

E. Off-Label Use of Infuse® in the Lumbar Spine is Not Safe or Effective

34. Questions about off-label use cropped up before the product was approved. For example, in early 2002, one member of an FDA advisory committee reviewing Infuse® asked agency staff for recommendations on "guarding against off-label use of this product."

35. A number of patients say they have been harmed in off-label uses of Infuse®, which is approved by the FDA only for anterior-approach surgery in a small section of the spine in the lower, or lumbar, region. At least 280 reports of adverse events involving Infuse® have been made to the FDA. Approximately 75% of those reports involve off-label use.

F. Despite Lack of Safety and Effectiveness, Medtronic Improperly Promoted and Marketed to Physicians the Off-Label Use of Infuse® Through a Posterior Approach

36. Medical device companies look for surgeons who are known as "Opinion Leaders" and who will use a high volume of their devices. Opinion leaders are physicians whose opinions on medical procedures and medical devices are held in high regard. If these influential physicians are willing to promote the use of a certain device, then other surgeons are likely to follow suit and use that device, sometimes including the improper promotion of off-label uses.

37. Many medical device companies, including Medtronic, cultivate relationships with these opinion leaders, paying them handsome (and in the case of

Infuse®, sometimes seven figure) consulting fees, travel expenses for seminars, and other perks, to encourage these physicians to promote the use of a particular medical device.

38. Not only did Medtronic engage in such activities with respect to Infuse®, it improperly paid doctors to promote, both directly and indirectly, the off-label use of Infuse® through the posterior and lateral approaches in lumbar spine fusions.

39. The Wall Street Journal, for example, has reported that Timothy Kuklo, M.D., while an orthopedic surgeon at Walter Reed Army Hospital, submitted an article to a British medical journal with fabricated claims of the efficacy of Infuse® and forged the signatures of four "co¬authors." Medtronic confirmed that Dr. Kuklo was a paid consultant for Medtronic and that the company has paid him over $800,000.

40. The Defendants here, MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC., have been named as defendants in two prior qui tam actions, United States ex ref. (UNDER SEAL) v. Medtronic. Inc., et al., Civil Action No. 02-2709 (W. D. Tenn.), and United States ex rel. Poteet v. Medtronic, Inc., et al., Civil Action No. 03-2979 (W. D. Tenn.) (collectively the "qui tam lawsuits"), both of which allege that Medtronic violated the False Claims Act, 31 U.S.C. § 3729, et seq., by paying illegal kickbacks to certain physicians in connection with promoting the off-label use of Infuse® in the spine, which resulted in the submission of false or fraudulent claims to federal health care programs.

41. In these lawsuits, the United States Department of Justice ("DOJ") contends that between January 1, 1998 and April 30, 2003, Medtronic made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products in the form of (1) payments and other remuneration for

physicians' attendance and expenses at medical education events, "think tanks", YIP/opinion leader events, and meetings at resort locations; (2) services and payments for services to physicians through Medtronic's Healthcare Economic Services and eBusiness Departments; and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with various physicians and entities.

42. Based on its investigation, the DOJ contends that certain of the payments, services, and remuneration mentioned above were improper and resulted in the submission of false or fraudulent claims.

43. In July 2006, Medtronic agreed to pay $40 million to the United States of America to settle these lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12.

44. As a result of this settlement, Medtronic and Medtronic Sofamor Danek agreed to enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

45. Also, as a result of this settlement, Medtronic agreed to negotiate with representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which Medtronic agreed to a settlement concerning the conduct at issue in the lawsuits.

46. Despite its 2006 settlement with the DOJ, and on information and belief, Medtronic has continued from 2006 to the present to improperly and illegally promote the off label use of Infuse® in non-FDA-approved spine surgeries.

G. September 30,2008 Letters from United States Senators Herb Kohl and Charles Grassley to Medtronic Regarding Ongoing Concerns over Medtronic's Payments to Doctors Related to the Promotion and Marketing of Infuse®

47. Despite this July 2006 Settlement with the DOJ, concerns regarding Medtronic's off-label marketing activities and related payments to doctors continued.

48. On September 30, 2008, U.S. Senator Herb Kohl sent a letter to Medtronic noting that earlier in 2008, Medtronic' s outside counsel provided to the Special Committee on Aging a written account of Medtronic's efforts to comply with the July 2006 Settlement Agreement it reached with the DOJ concerning allegations that Medtronic and its subsidiary improperly compensated surgeons and physicians in connection with the Infuse® device.

49. Senator Kohl's letter expressed several concerns, including the following:

That account also addressed the corporate integrity agreement (CIA) that Medtronic and its subsidiary entered into with the Office of the Inspector General of the United States Department of Health and Human Services stemming from those same allegations. In that same letter to the Committee, Medtronic and its subsidiary both denied that "improper payments were made to physicians in the first place (Medtronic's agreement with DOJ does not contain any admission of liability), much less that improper payments 'have continued.'" Consequently, it was with concern that I read recent articles, in the Wall Street Journal and elsewhere, which outlined highly disturbing allegations of improper, if not illegal, payments by Medtronic to surgeons and physicians. These continuing allegations are directly relevant to the Committee's oversight of inappropriate

physician compensation practices within the medical device industry. All of the major orthopedic device companies that settled with DOJ over such allegations were required to publicly reveal information related to their payments to physicians. Medtronic's response to the Committee's initial inquiry articulated no specific reasons as to why Medtronic has yet to voluntarily make the same disclosures.

50. In this letter, Senator Kohl requested both documentation of Medtronic's efforts to comply with the July 2006 Settlement Agreement and interviews with corporate witnesses and documents "given the ongoing, serious concerns publicly raised regarding the integrity and transparency of Medtronic' s physician compensation practices."

51. Senator Grassley went on to express his concern over the Wall Street Journal's reports "that one of the incentives Medtronic provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product."

52. This letter specifically addressed issues related to Medtronic's marketing of Infuse®:

> Fourth, earlier this month the WSJ reported on problems with off-label use of Medtronic's Infuse®. Infuse® is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that Medtronic gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of Infuse®. The allegations that Medtronic has been disguising these consulting agreements as inducements or kickbacks for physicians to use Infuse® are equally troubling. Likewise, this is a practice that I would like to better understand and I would like to know what if anything has changed since these reported events.

53. Senator Grassley, in his September 30, 2008 letter, also questioned why several lawsuits against Medtronic pertaining to Infuse® remained under seal, and indicated that he would like to "better understand the status of these lawsuits and the procedural process that has led to the current situation." continued to misrepresent the adverse events that result from Infuse® and rhBMP-2, as well as the possibility that Medtronic improperly influenced clinical trials and reporting regarding rhBMP-2. On June 21, 2011, Senators Charles Grassley and Max Baucus sent a letter to Medtronic on behalf of the Senate Committee on Finance requesting Medtronic produce documents and communications pertaining to "adverse postoperative events and/or medicalcomplications" resulting from the use of rhBMP-2. The letter also requests Medtronic provide "[a] detailed account of payments that Medtronic made to all Infuse clinical investigators."

54. In the June 21 letter, Senators Grassley and Baucus state: "We are extremely troubled by press reports suggesting that doctors conducting clinical trials examining the safety and effectiveness of Infuse on behalf of Medtronic were aware that Infuse, a treatment commonly used in spinal surgery, may cause medical complications, but failed to report this in the medical literature. This issue is compounded by the fact that some clinical investigators have substantial financial ties to Medtronic."

55. The letter further states: "We are also concerned that other severe side-effects of Infuse and similar bone-growth products developed by Medtronic may have been unreported or under-reported in clinical literature. Reports have linked Infuse to potentially fatal swelling in the neck and throat, and radiating leg pain. Concerns have also been expressed about a potential link to cancer."

I. June 1, 2011 Issue of The Spine Journal

56. On June 1, 2011, The Spine Journal, a leading medical journal in the United States, published a special edition dedicated to addressing serious patient safety concerns and ethical concerns related to the use of rhBMP-2 (Infuse®) in the spine.

57. This special edition reviewed thirteen peer-reviewed articles about rhBMP-2 by industry-sponsored authors, including many sponsored by Medtronic, and found that these articles had inaccurately reported the safety of rhBMP-2 applications by underestimating its risks.

58. In an editorial summarizing the findings of the special issue, five prominent physicians, including spine surgeons at Stanford University, wrote that the earlier industry sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2- related clinical adverse events." For example, the industry-sponsored articles omitted mention of indications from the earliest trials of inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. They also omitted mention of sterility and cancer risks associated with rhBMP-2, as reported in FDA documents and hearings. The trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review/publication shortfalls.

59. According to this editorial and several of the accompanying articles, the thirteen industry-sponsored articles reported only successful fusions and low rates of complications with Infuse®, which led to the "off-label" use of Infuse® as an adjunct to increase early fusion rates in lumbar fusion procedures. The articles "may have promoted widespread poorly considered on and off-label use, eventual life-threatening complications and deaths."

60. Contrary to the conclusions of the earlier industry-sponsored trials and articles, an article in the special issue suggested "an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach." Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. Posterior lumbar inter body fusion was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes. In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy." Eugene J. Carragee, Eric L. Hurwitz & Bradley K. Weiner, A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned, 11 Spine J. 4 71, 4 71-72 (20 11) (emphasis added).

61. This article also reported that ten of the earlier industry-sponsored rhBMP-2 trials were funded in whole or in part by the manufacturer of rhBMP-2 (Infuse®), Medtronic, Inc. Furthermore, in twelve of these earlier studies, the median-known financial association between the authors and Medtronic Inc. was approximately$12,000,000-$16,000,000 per study(range, $560,000¬$23,500,000). Id. at 475.

J. CLINTON THORN's Initial Surgery, and Revision Surgery

62. On March 4, 2010, CLINTON THORN had a posterior lumbar interbody fusion surgery at the L5 - S1 spine to correct a degenerative disc condition.

63. During the surgery, Dr. Christopher Hulen used an off-label posterior approach to place the Medtronic Infuse® bone graft into the lumbar region of CLINTON THORN's spine in order to attempt to fuse vertebrae S 1 to L5.

64. In or about October 2011, CLINTON THORN was symptomatic and experiencing pain and limitations related to his back. He presented for MRI, CT scan which identified Ectopic bone, Bone overgrowth, Osteophyte formations compressing his nerves at L5-S1, the location where he was implanted with Infuse®.

65. On April 24, 2012, CLINTON THORN had revised interbody fusion performed by Dr. Mroz at the Cleveland Clinic in Cleveland, Ohio.

66. CLINTON THORN continues to suffer significant pain, and disability as a result of his exposure to Infuse.

IV. SUMMARY OF ALLEGATIONS

67. Plaintiff, CLINTON THORN, suffered grievous personal injuries as a direct and proximate result of Defendants' misconduct.

68. CLINTON THORN would not have chosen to be treated with Infuse® had he known of or been informed by Defendants of the true risks of the off-label use of Infuse®.

69. At all relevant times, Infuse® was researched, developed, manufactured, marketed, promoted, advertised and sold by the Medtronic Defendants.

70. At all times relevant, the Medtronic Defendants misrepresented the safety of Infuse® to physicians and patients, including CLINTON THORN, and recklessly, willfully, or intentionally failed to alert CLINTON THORN or his physicians of the extreme danger to patients of the off-label use of Infuse® through a posterior approach.

71. At all times relevant, the Medtronic Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed Infuse® as a safe and effective device to be used for spinal fusion surgery. Medtronic negligently, recklessly, and/or intentionally over promoted Infuse® to physicians and consumers, including Dr. Christopher Hulen and CLINTON THORN, and downplayed to physicians and consumers its dangerous effects, including but not limited to the over promotion and downplaying of the dangerous effects of Infuse® in off-label posterior approach spine surgeries.

72. Any warnings Medtronic may have issued concerning the dangers of off-label use of Infuse® through a posterior approach were insufficient in light of

Medtronic's contradictory prior, contemporaneous and continuing promotional efforts and over promotion of Infuse® for off-label posterior-approach use in the lumbar spine.

73. At all relevant times, Medtronic knew, and/or had reason to know, that Infuse® was not safe for off-label use on patients because it had not been approved for posterior approach use; and its safety and efficacy for posterior-approach use was either unknown, or was known by these Defendants to be unsafe.

74. In posterior-approach lumbar spine surgeries, Infuse® often leads to serious complications including, but not limited to, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes, and as in Plaintiff CLINTON THORN's case, pain and/or weakness in limbs caused by bone growth.

75. When used in posterior-approach lumbar spine surgery, Infuse® has often failed to work in a safe and effective manner, and was defective, thereby causing serious medical problems and, in some patients, like CLINTON THORN, catastrophic injuries.

76. At all relevant times, Medtronic knew, and/or had reason to know, that its representations and suggestions to physicians that Infuse® was safe and effective for use in posterior-approach lumbar spine surgery were materially false and misleading.

77. The off-label posterior-approach use of Infuse® can cause serious physical injuries and/or death.

78. Medtronic knew and/or had reason to know of this likelihood and the resulting risk of injuries and deaths, but concealed this information and did not warn CLINTON THORN or his physicians, preventing Plaintiff and his physicians from making informed choices in selecting other treatments or therapies.

79. Plaintiff and his physicians relied on Medtronic's misrepresentations regarding the safety and efficacy of Infuse® in connection with their decisions to use Infuse® off-label in Plaintiffs spine surgery. Plaintiff and his physicians did not know of the specific risks, and/or were misled by Medtronic as to the nature and incidence of the true specific risks, and/or knew of the true risks and chose to not inform Plaintiff of those risks, related to the use of Infuse® in posterior-approach lumbar spine surgeries.

80. The Medtronic Defendants improperly promoted and marketed Infuse® to Plaintiff's physicians for off-label use in the spine, and this promotion and marketing caused Plaintiff's physicians to decide to implant Infuse® in Plaintiff's spine using a posterior approach.

81. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of the other Defendant herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendant, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

82. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all Defendants and each of them, thereby ratified those actions.

83. There exists and, at all times herein mentioned there existed, a unity of interest in ownership between Defendants such that any individuality and separateness

between the Defendants has ceased and these Defendants are the alterego of the other Defendant and exerted control over that Defendant. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

84. At all times herein mentioned, the Medtronic Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff and his physicians. As such, each of the Medtronic Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for his damages.

85. The harm which has been caused to Plaintiff resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiff. There may be uncertainty as to which one or a combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or a combination of Defendants caused Plaintiff's injuries.

COUNT I. Breach of Express and Implied Warranty

86. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

87. At all times herein referenced, Medtronic utilized journal articles, advertising media, sales representatives, consultants and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of Infuse® and expressly and impliedly warranted to physicians and other members of the general public and medical community that such off-label uses, including uses in posterior procedures was safe and effective.

88. Medtronic knew or, in the exercise of reasonable diligence, should have known that such off-label uses had the serious side effects set forth herein;

89. Plaintiff's physician, Christopher Hulen, relied on Medtronic's express and implied warranty representations regarding the safety and efficacy of off-label use of Infuse®, but such off-label uses, including uses in posterior lumbar interbody fusion procedures, were not effective, safe, and proper for the use as warranted in that it failed and lead to unwanted exuberant bone growth and was dangerous when put to its promoted use.

90. As a direct and proximate result of Defendants' wrongful conduct as set forth above, Plaintiff was exposed to Infuse® causing his injuries as described herein.

COUNT II - Negligence

91. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

92. Defendants marketed their Infuse® product to and for the benefit of Plaintiff, and additionally marketed it to his physicians, and these Defendants knew or

should have known that Plaintiff and his physicians would use their product, including for the off-label use of posterior approach lumbar spine fusion.

93. Defendants owed Plaintiff and his physicians duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

94. Defendants had a confidential and special relationship with Plaintiff due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to Infuse®, and (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for posterior-approach lumbar spine surgeries.

95. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiff and his physicians of the true health and safety risks related to the off-label use of Infuse®, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for posterior-approach lumbar spine fusion surgery. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of Infuse® to Plaintiff and his physicians.

96. Misrepresentations made by Defendants about the health and safety of Infuse® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and his physicians the true health and safety risks related to Infuse®, and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices.

97. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff and to his physicians.

98. The following sub-paragraphs summarize, inter alia, Defendants' breaches of duties to Plaintiff and his physicians and describe categories of acts or omissions constituting breaches of duty by these Defendants. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

a. Unreasonable and improper promotion and marketing of Infuse® to physicians, including but not limited to the promotion and marketing of Infuse® for off-label use in posterior-approach lumbar spine fusion surgeries;

b. Failure to warn physicians and Plaintiff of the dangers associated with Infuse® when used off-label in posterior-approach lumbar spine surgery including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments.

c. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse®.

99. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiff and his physicians would use and did use Infuse®, to the detriment of Plaintiffs health, safety and well-being.

100. As the direct, producing, proximate and legal cause and result of the Defendants' negligence, Plaintiff suffered severe injuries.

101. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

102. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

103. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

104. As a direct and proximate result of Defendants' wrongful conduct as set forth above, Plaintiff was exposed to Infuse® causing his injuries as described herein.

COUNT III - Failure To Warn

105. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

106. Medtronic had a duty to warn Plaintiff and his physicians about the dangers of Infuse® of which they knew, or in the exercise of ordinary care, should have known, at the time the Infuse® left the Defendants' control. The Medtronic Defendants did know of these dangers of off-label use of Infuse®, and breached this duty by failing to warn Plaintiff and his physicians of the dangers of its off-label use in posterior-approach lumbar spine surgery.

107. The warnings accompanying the Infuse® product did not adequately warn Plaintiff and his physicians, in light of its scientific and medical knowledge at the time, of

the dangers associated with Infuse® when used off-label in posterior-approach lumbar spine surgery including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments.

108. The warnings accompanying the Infuse® product failed to provide the level of information that an ordinary physician or consumer would expect when using the product in a manner reasonably foreseeable to Medtronic. Medtronic either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the off-label use of Infuse®, including but not limited to these risks of ectopic or uncontrolled bone growth.

109. Plaintiff and his physicians relied on Medtronic' s inadequate warnings in deciding to use Infuse® in an off-label manner. Plaintiff and his physicians would not have made off-label use of Infuse® for posterior-approach lumbar spine fusion surgery had they known of the safety risks related to Infuse®.

110. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, and of Medtronic's failure to provide adequate warnings about them, Plaintiff sustained serious injuries of a personal and pecuniary nature in the present and in the future. Plaintiff is therefore entitled to fair and reasonable damages in an amount to be proven at trial, together with interest thereon and costs.

111. Plaintiff has sustained extreme pain, suffering, and anguish from the date of his posterior-approach lumbar spine surgery with Infuse® until present and in the future. Plaintiff is therefore entitled to fair and reasonable damages in an amount to be proven at trial, together with interest thereon and costs.

112. As a direct and proximate result of Defendants' wrongful conduct as set forth above, Plaintiff was exposed to Infuse® causing his injuries as described herein.

IV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, CLINTON THORN prays for judgment against Defendants for a fair and reasonable amount of compensatory damages and general damages, economic and non¬economic, sustained by Plaintiff against all Defendants, jointly and severally, in an amount to be determined at trial. Plaintiff additionally prays for an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees and for such other and further relief as the Court deems equitable or appropriate.

Request Jury Trial.

Respectfully submitted,

March 1, 2013 Clint J. Thorn

CLINTON THORN, *pro se*

Written with assistance of counsel